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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,026	11/21/2003	Madaline Chirica	DX01074B1K	3154

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/720,026	CHIRICA ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 (in part), 2-4, 5 (in part), 6, 8 and 9, drawn to a method of treating a human subject experiencing a physiological disorder comprising administering an effective amount of an antagonist of DCRS5, classified in class 514, subclass 12.

II. Claims 1 (in part), 2-4, 7(in part) and 8, drawn to a method of treating a human subject experiencing a physiological disorder comprising administering an effective amount of an agonist of DCRS5, classified in class 514, subclass 12.

III. Claims 1 (in part), 2-4, 5 (in part), 6, 8 and 9, drawn to a method of treating a human subject experiencing a physiological disorder comprising administering an effective amount of an antagonist of P19, classified in class 514, subclass 12.

IV. Claims 1 (in part), 2-4, 7(in part) and 8, drawn to a method of treating a human subject experiencing a physiological disorder comprising administering an effective amount of an agonist of P19, classified in class 514, subclass 12.

V. Claims 10-17, drawn to a method of diagnosing a physiological disorder contacting a binding composition that specifically binds to DCRS5, wherein composition contains an antibody, classified in class 436, subclass 501.

VI. Claims 10-17, drawn to a method of diagnosing a physiological disorder contacting a binding composition that specifically binds to p19, wherein composition contains an antibody, classified in class 436, subclass 501.

VII. Claims 10-17, drawn to a method of diagnosing a physiological disorder contacting a binding composition that specifically binds to DCRS5, wherein composition contains a nucleic acid, classified in class 435, subclass 6.

VIII. Claims 10-17, drawn to a method of diagnosing a physiological disorder contacting a binding composition that specifically binds to p19, wherein composition contains a nucleic acid, classified in class 435, subclass 6.

IX. Claims 10-17, drawn to a method of diagnosing a physiological disorder contacting a binding composition that specifically binds to DCRS5, wherein composition contains a detectable label, classification unknown.

X. Claims 10-17, drawn to a method of diagnosing a physiological disorder contacting a binding composition that specifically binds to p19, wherein composition contains a detectable label, classification unknown.

The inventions are distinct, each from the other, for the following reasons:

Inventions I-X are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of

operation, function, or effect. See MPEP § 806.05(j). Groups I-X are different methods requiring different methods steps, wherein each is not required, one for another. For example, Invention I requires search and consideration of a method of treating a human subject experiencing a physiological disorder comprising administering an effective amount of antagonists of DCRS5, which is not required by the other inventions. Invention II requires search and consideration of a method of treating a human subject experiencing a physiological disorder comprising administering an effective amount of agonists of DCRS5, which is not required by the other inventions. Invention III requires search and consideration of a method of treating a human subject experiencing a physiological disorder comprising administering an effective amount of antagonists of p19, which is not required by the other inventions. Invention IV requires search and consideration of a method of treating a human subject experiencing a physiological disorder comprising administering an effective amount of agonists of p19, which is not required by the other inventions. Invention V requires search and consideration of a method of diagnosing a physiological disorder contacting a binding composition comprising antibodies that specifically binds to DCRS5, which is not required by the other inventions. Invention VI requires search and consideration of a method of diagnosing a physiological disorder contacting a binding composition comprising antibodies that specifically binds to p19, which is not required by the other inventions. Invention VII requires search and consideration of a method of diagnosing a physiological disorder contacting a binding composition comprising nucleic acids that specifically binds to DCRS5, which is not required by the other inventions. Invention VIII

requires search and consideration of a method of diagnosing a physiological disorder contacting a binding composition comprising nucleic acids that specifically binds to p19, which is not required by the other inventions. Invention IX requires search and consideration of a method of diagnosing a physiological disorder contacting a binding composition comprising a detectable label that specifically binds to DCRS5, which is not required by the other inventions. Invention X requires search and consideration of a method of diagnosing a physiological disorder contacting a binding composition comprising a detectable label that specifically binds to p19, which is not required by the other inventions.

Furthermore, the distinct steps and products require separate, distinct, and non-overlapping coextensive searches. As such, it would be burdensome to search the inventions of Groups I-X together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

2. This application contains claims directed to the following patentably distinct species: The physiological disorders disclosed are all immune related. However, the diseases have different pathologies and different mechanisms. A method of treating or diagnosing a physiological disorder wherein the disorder comprises:

a. rheumatoid arthritis;

b. asthma or allergy;

c. chronic obstructive pulmonary disorder (COPD);

d. an interstitial lung disorder (idiopathic pulmonary fibrosis, eosinophilic granuloma or hypersensitivity peumonitis);

e. an inflammatory bowel disorder (Crohn's disease or ulcerative colitis);

f. an inflammatory skin disorder (psoriasis or atopic dermatitis)

The species are independent or distinct because each of the of the diseases (a)-(f) have different pathologies and different mechanisms. The species are independent or distinct because each requires separate, non-coextensive searches. For example, a technical literature search for treating or diagnosing chronic obstructive pulmonary disorder (COPD), may not result in relevant art with respect to treating or diagnosing an inflammatory bowel disorder (IBD).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1and 10 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3.The claims of Groups I-XI are drawn to multiple sequences (SEQ ID NOs: 1, 2, 5 and 6). Each of the different sequences are independent and distinct because no common structural or functional properties are shared. Accordingly, these sequences are each subject to restriction under 35 U.S.C. § 121. Regardless of the Group elected, Applicant is additionally required to elect a single polypeptide sequence, which if determined to be patentable, would also be patentably distinct from the other polypeptide sequences. This requirement is made under 1192 O.G.68 Notice (November 19, 1996), as examination of more than one sequence in one application would result in an undue burden on the PTO.

4. In addition, Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant in addition to electing from Inventions I-X, one species from disease group (a)-(f) must also be chosen to be considered fully responsive.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS
Art Unit 1647
September 16, 2006

Jegatheesan Seharaseyon
Patent Examiner